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EXAMINER

POPOVICS, ROBERT J

ART UNIT PAPER NUMBER

1724

DATE MAILED: 03/13/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/385,405

Applicant(s)

Schmidt

Examiner

Popovics

Group Art Unit

1724

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- ☒ Responsive to communication(s) filed on 12/23/02 (Appel Brief)
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 71-83 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 71-83 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement

Application Papers

- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some* ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) Filed 4/1/01
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1724

DETAILED ACTION

1. In view of the Appeal Brief filed on December 23, 2002, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 71-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 71 now recites ***“said waste material containing at least one first component which can not effectively be separated from the first liquid into a non-solvent***

Art Unit: 1724

based layer.” This recitation is unsupported by the originally filed specification. Newly submitted claim 72 goes on to claim ***“The method of claim 1 wherein the first component is selected from oily type materials, particulates and combinations thereof having an affinity for the solvent.*** The specification does not say anything about any materials having ***“an affinity for the solvent.”*** These recitations constitute new matter.

4. Claim 72 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant’s originally filed specification fails to teach those skilled in the art how to differentiate between those ***“particulate and/or oily type”*** contaminants of a trace nature from those having an affinity for the solvent based layer, and **now** asserted to be the subject of invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 71-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 71, it is unclear what Applicant intends by the recitation ***“said waste material containing at least one first component which can not effectively be separated from the first liquid into a non-solvent based layer.”*** It is unclear what Applicant intends by

Art Unit: 1724

“effectively,” in the context used. Is this intended to refer to residual or trace amounts? It is unclear why this *“first component”* cannot be effectively separated.

Applicant has argued (Response - Paper no. 26):

Reference is first made to page 13, lines 11-13 wherein it is stated that the separated solvent based layer (e.g., aqueous layer) contains particulates and/or oily type materials (the contaminants of interest in the present invention). (Response pg. 7, lines 8-10)

As will become more fully apparent from the discussion below, the present invention is principally concerned with removing those contaminants which reside in the solvent based layer and not in the non-solvent based layer which is the subject of the reference cited herein (U.S. Patent No. 5,288,408). (Response pg. 7, lines 17-21)

These arguments have raised new issues requiring clarification. With respect to the first sentence, Applicant has positively asserted that *“the solvent based layer (e.g., aqueous layer) contains particulates and/or oily type materials (the contaminants of interest in the present invention).”* In other words, Applicant has asserted that at least one of these components is necessarily present. This is inconsistent with the specific portion of the specification referenced by Applicant. The referenced sentence (i.e., page 13, lines 11-13) begins with the word *“If.”* Specifically, the sentence appearing at page 13, lines 11-13 reads: **“If the separated aqueous layer contains particulates and/or oily type materials, the aqueous layer may then be treated, to remove residual oils and/or particulates by means of hot filtration processes as more fully described below.”** Given that there may not be any of the *“the contaminants of interest in the present invention”* present, as Applicant’s specification makes clear, the meaning of claim 71 and those claims dependent thereon, is unclear, when those contaminants are not present. Moreover, it is unclear how one skilled in the art would differentiate between the two different types (i.e., those having an affinity for the solvent based layer, and those not having said

Art Unit: 1724

affinity) of contaminants argued to be present in Applicant's most recent response, since Applicant's **originally filed** specification makes no such distinctions. In other words, it is unclear how potential infringers would be put on notice.

7. Claims 71-83 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 71-83 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Applicant's specification at page 4, lines 1-16, and page 5, lines 3-8. There, Applicant has stated (when discussing the Schmidt et al. Patent - U.S. Patent No. 5,288,408) **"A pure, concentrated aqueous gelatin-glycerin solution results which may be stored or further prepared for immediate reuse. Although this process lends itself to the removal of dyes and active ingredients with additional chemical reactions and processing, such dyes, active ingredients, and glycerin are not removed *in situ*,"** and this statement indicates that the invention is different from what is defined in the claim(s) because the claims fail to mention anything about being **"*in situ*."** One skilled in the art reading the cited portions of the specification would clearly agree that Applicant had admitted that recycling gelatin-based encapsulation waste material using the method disclosed in the '408 patent resulted in **"A pure, concentrated aqueous gelatin-glycerin solution,"** but that Applicant's instant invention somehow involved **"*in situ*"** processing.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1724

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 71-73, 75-81 and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt (US 5,288,408).

10. In the '408 patent to Schmidt, one of the objects is stated to be:

Still another object of the present invention is to provide a recycled gelatin product with chemical and physical properties identical to virgin gelatin such that reuse may be successfully accomplished.

11. At column 3, the following is disclosed:

The soft elastic capsule-forming material will thus be used to enclose active ingredients in the form of powders, liquids or combinations thereof. Oils, such as vitamin A, vitamin E and beta-carotene, for example, are frequently encapsulated in the pharmaceutical industry. Additionally, other oils like mineral oil may be used to coat the outer surface of the gel-capsule during processing. Thus, it can be seen that the encapsulation waste product may have many components to be removed for reuse. In some instances, coloring agents and preservatives may also be incorporated into the encapsulation melt. Commonly used preservatives are methyl- and propylparabens and sorbic acid.

As stated above, present methods of encapsulation lose as much as 50% of the melt during processing, the balance of which is either discarded as a waste by-product or recycled. The latter option requires the removal of all of the above components with the exception of gelatin and glycerine. The present invention provides a novel and efficient method of accomplishing same without experiencing the shortcomings of the prior art.

12. At column 4, lines 22-31, it is disclosed that:

Next, the lower phase is hot filtered to remove any remaining traces of oil or other contaminants. Stainless steel filtration equipment may be employed such as a plate filter, or a coated plate filter like, for example, a Sparkler filter. Alternatively, nutche filters of the Rosenmund type or cartridge filters may be used for the purpose. Here again, the residue may be recaptured for further separation and purification if desired although the amounts involved at this point may not warrant the effort.

Art Unit: 1724

13. Claim 6 teaches:

6. The process for recovering and purifying waste gelatin and glycerine of claim 1, wherein the step of hot filtering said aqueous gelatin/glycerine solution is accomplished by use of one of the following filters: (a) a plate filter; (b) a coated plate filter; (c) a nutche filter; or (d) a cartridge filter.

14. Claim 20 teaches:

20. The apparatus of claim 12 wherein said means for hot filtration is a cartridge filter.

15. In order to remove *“all of the above components,”* including *“traces”* of *“coloring agents,”* *“oils and other contaminants,”* from the lower aqueous phase (i.e., “solvent based phase”) to attain a *“recycled gelatin product with chemical and physical properties identical to virgin gelatin,”* any *“cartridge filter”* used would necessarily have the ability, regardless of the filtration process label placed upon it, to accomplish this task. That is to say that any *“cartridge filter”* used would have inherently possessed the ability to accomplish the stated objective. The ‘408 patent is clear, that a *“cartridge filter”* may be used *“to remove any remaining traces of oil or other contaminants”* from the aqueous/lower phase!

With respect to claim 72, the ‘408 process will inherently remove all particulate and oily type contaminants. With respect to claim 76, it is submitted that the specified range of “up to 5 volumes” corresponds to a solution having a “preferred concentration of 10% to 12% gelatin/glycerine by weight,” since this is disclosed by Schmidt et al. as “the optimum concentration for achieving rapid and thorough separation of the two layers” at column 3, lines 60-65.

Art Unit: 1724

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 71-73, 75-81 & 83 are alternatively rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (U.S. Patent No. 5,288,408).

Schmidt et al. disclose a method of gelatin recovery. As illustrated in Fig. 1, waste material is dissolved with a solvent in an agitated tank and separated into an aqueous/lower phase stream and an upper/organic phase stream. The resultant aqueous phase stream is then subjected to heat and hot filtered, *"to remove any remaining traces of oil or other contaminants."* A resultant gelatin/glycerine filtrate is then heated and subjected to vacuum distillation in order to concentrate (i.e., dewater) the resultant, purified filtrate. The recovered gelatin and glycerine may then be immediately re-used (col. 2, lines 33-35 & col. 5, lines 5-10). Beyond disclosing the use of a "cartridge filter" as one possible type of filter to be used, the '408 patent does not go into the details of the pore size, material of construction, etc., of a "cartridge filter" which would be suitable for the stated purpose. Obviously, no such details were provided, since Schmidt et al. knew that the selection of a such filter would have been well within the purview of the skilled artisan. Indeed, numerous filters existed prior to issuance of the '408 patent which could have handled the separation of "trace" amounts of oil, or "other contaminants" from a liquid stream.

Art Unit: 1724

Claim 76 specifies a dilution volume "of up to 5 volumes of said solvent." Schmidt et al. do not express the dilution in terms of volumes, but rather, they disclose "the optimum concentration for achieving rapid and thorough separation of the two layers" at column 3, lines 60-65.. It is submitted that one of ordinary skill in the art obviously would have been able to handle the conversion, in order to express the optimum concentration in terms of dilution volumes, in order to obtain optimum separation.

18. Claims 74 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of **Schmidt et al.** (U.S. Patent No. 5,288,408) and **Dutre et al.** (Purification of Gelatin by Ultrafiltration with a Forced Solvent Stream along the Membrane Permeate Side: An Experimental Approach - Journal of Food Engineering © 1995).

Schmidt et al. do not expressly disclose the use of tangential flow filtration as recited in claim 74, or ultrafiltration as recited in claim 82. Dutre et al. disclose the use of tangential flow tubular membrane ultrafiltration to concentrate Gelatin (see Fig 1(b)). Page 234 of Dutre et al. discloses the benefits associated with ultrafiltration concentration of the gelatin solution, namely, lower costs and higher purity. Accordingly, it would have been obvious to concentrate the gelatin solution of Schmidt et al., using an ultrafilter in order to obtain a concentrated gelatin solution.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Art Unit: 1724

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 71-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12,14-16 and 18-20 of U.S. Patent No. 6,361,802. Although the conflicting claims are not identical, they are not patentably distinct from each other because, while the ***“to for including”*** language of “step “a)” of the ‘802 patent is not understood by the Examiner, it is submitted that the claims of the ‘802 patent are drawn to the treatment of same ***“waste material containing gelatin”*** presently being claimed. The claims of the ‘802 patent differ only in semantics, - not substance. The claims of the ‘802 patent refer to ***“capsules,”*** while the instant claims recite ***“waste material containing gelatin.”*** In particular, it is noted that the term ***“capsule,”*** has been defined in the specification of the of the ‘802 patent as ***“any capsules obtained from a capsule producing process which are not saleable for reasons including, but not limited to, cloudiness, malformation, incorrect fill quantity, or expired commercial lots returned to the manufacturer.”*** One skilled in the art would have obviously

Art Unit: 1724

appreciated that such “*malformed*” or “*cloudy*” capsules would constitute or be called “*waste material*,” since they obviously weren’t saleable.

Response to Arguments

21. Applicant's arguments filed February 11, 2002 have been fully considered but they are not persuasive.

The 5,288,408 patent to William J. Schmidt, Michael F. Smith and James W. Neal III is prior art under 35 USC 102(b). That patent issued February 22, 1994, more than four years prior to November 16, 1998, the date of the earliest claimed priority application - 60/108,584.

The 5,288,408 patent to William J. Schmidt, Michael F. Smith and James W. Neal III was used as a blueprint in drafting the instant application. Large and numerous portions of text present in the ‘408 patent appear verbatim in the instant application. In this light, many of the arguments present in the Brief, and throughout the prosecution are incomprehensible, demonstrating an apparent complete miscomprehension of the ‘408 patent.

Applicant’s arguments are now considered in view of these facts.

Applicant completely mis-characterizes the essence of *his prior* patent at page 15, lines 5-8 of the Appeal Brief (Paper No. 32).

“What is important is that Applicant’s invention is directed to the treatment of the solvent based layer; not to the treatment of the non-solvent based layer which is the subject of the invention described in the sole prior art reference cited against the present claims.”

It is incomprehensible how such an argument could be made by Applicant when discussing *his own prior patent!* The ‘408 patent treats the same layer that the instant claimed invention

Art Unit: 1724

treats - THE SOLVENT BASED LAYER (see, for example, col. 4, lines 22-30 of the '408 patent). Also see the SUMMARY OF THE INVENTION (col. 2, lines 15-35).

Regarding the new matter rejection, Applicant argues (pages 11-12 of Brief):

This language was incorporated into claim 71 to emphasize the material distinctions between the claimed invention and the Schmidt et al. prior art reference which concerned treatment of the non-solvent based layer

Language has now been added to emphasize "*material distinctions*" over Applicant's own prior patent which issued in 1994, and which was used as a blueprint for the instant application. Of course, Applicant's own prior patent doesn't use this language, because it was added with claim 71. If the new language does not constitute new matter, then the same language should flow from the '408 patent, since the disclosures are almost the same

Conclusion

22. This action is NOT FINAL.

23. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Robert Popovics whose telephone number is (703) 308-0684.



**Robert James Popovics
Primary Examiner
Art Unit 1724**

rjp
March 8, 2003